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EXAMINER	
KIM, YOUNG J	

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 01/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/043,573	LEMIEUX ET AL.	
	Examiner	Art Unit	
	Young J. Kim	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-15 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-15 is/are rejected.

7)☒ Claim(s) 1-15 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 09 January 2002 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 4/9/03
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: Sequence Alignment..

DETAILED ACTION

The Examiner of record has been changed. All further correspondence regarding this application should be directed to Examiner Young J. Kim whose Group Art Unit is 1637.

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-15 and SEQ ID NO: 57 in the reply filed on January 5, 2004 is acknowledged. The traversal is on the ground(s) that in both parent applications, ten sequences were searched apparently without undue burden and that the prosecution was "extremely brief", citing MPEP 803.04 that, "normally ten sequences constitute a reasonable number for examination purposes." (page 1, response). This is not found persuasive for the following reasons. With regard to the search conducted on the parent applications, the argument is not found persuasive because the previous applications were examined by another examiner and as all applications are examined according to their merits, the Examiner of record for the instant application maintains that it would require undue search burden to search all of the sequences appearing in Table 1.

Additionally, MPEP 803.04 also states that, "[a]ccordingly, in most cases, **up to** ten independent and distinct nucleotides sequences will be examined..." For PTO to search and examine a single SEQ ID Number, a SEQ ID Number must be searched against all databases in public domain, followed by a search in the databases of the issued patent and published, followed by the search in the unpublished (or pending/interference) database. As the claimed nucleic acid is drawn to a polymorphism, the query must be performed for all of the databases for a particular polymorphism, then repeated for another polymorphism. In order to search **and** examine ten SEQ ID Numbers, comprising polymorphisms, in all of the above-recited databases,

would amount to an enormous search burden. Finally, MPEP 803.04 states that, "[I]n some exceptional cases, the complex nature of the claimed material...may necessitate that reasonable number of sequences to be selected be less than ten."

As already discussed the search **and** examination required is considered to be complex and therefore, restriction to a single SEQ ID Number is maintained.

The requirement is still deemed proper and is therefore made FINAL.

Drawings

The drawing received on January 9, 2002 is acceptable.

Specification

The specification is objected to by the Examiner because it makes reference to an URL on the internet. For example, line 30f page 7contains web-address. While information on web-address is accessible, the embedded hyperlinks and/or other forms of browser-executable code are impermissible and require deletion. The attempt to incorporate subject matter into the patent application by reference to a hyperlink and/or other forms of browser-executable code is considered to be an improper incorporation by reference. See MPEP 608.01(p), paragraph I regarding incorporation by reference.

If the subject matter which is improperly incorporated by reference is directed to nonessential material (illustrating the state of the art), the deletion will probably not be considered as new matter. However, if the subject matter which is improperly incorporated by reference is directed to essential material, applicant will be required to amend the specification to

include the subject matter incorporated. The amendment must be accompanied by an affidavit or declaration executed by the applicant stating that the amendatory material consists of the same material incorporated by reference.

Claim Objections

Claims 1-15 are objected to for being drawn to non-elected SEQ ID Numbers. Amending the claims to recite only the elected SEQ ID Numbers would overcome this objection.

Claim 10 is objected to for containing a typographical error. Specifically, in the phrase, "wherein the ***a*** central position of the probe," it appears that the word, "a" should be deleted and the claim amended to recite what is meant by "central position".

Claim Interpretation

Absent a clear and explicit definition from the specification regarding what is meant by the term, "polymorphic site," the broadest reasonable interpretation of said term is given as any nucleic acid which comprises at least a nucleotide base that is different from that which is claimed (i.e., the elected SEQ ID Numbers).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 recites the phrase, "wherein the 3' end of the primer aligns with ***the*** polymorphic site of ***the*** segment." The term, "the segment" lacks proper antecedent basis. Additionally, it is indefinite because the phrase recites that a specific single polymorphic site is aligned to by the primer (denoted by the phrase, "the polymorphic site), it becomes unclear what and where this polymorphic site is.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-7 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claim 1 is drawn to, "[a] nucleic acid segment comprising at least 10 contiguous nucleotides identified in Table 1. Claims 2-7 further limit the above nucleic acid by varying number of contiguous nucleotides said nucleic acid comprises, and whether the nucleic acid is DNA or RNA.

Without a clear and specific definition from the specification, the term, "segment" does not further limit the nucleic acid so long as the requisite number of contiguous nucleotides are met. Such claim language would embrace a nucleic acid that is occurring in nature so long as the nucleic acid comprises said requisite number of nucleotides.

Amending the independent claim to become drawn to "***An isolated*** nucleic acid segment" would overcome this rejection.

Claims 1-15 are rejected under 35 U.S.C. § 101 because the claimed invention lacks patentable utility due to its not being supported by either specific and/or substantial utility or a well established utility.

Definitions: [from REVISED INTERIM UTILITY GUIDELINES TRAINING MATERIALS; repeated from http://www.uspto.gov/web/menu/utility.pdf, also available MPEP 2107.01]

> "Credible Utility" - Where an applicant has specifically asserted that an invention has a particular utility, that assertion cannot simply be dismissed by Office personnel as being "wrong". Rather, Office personnel must determine if the assertion of utility is credible (i.e., whether the assertion of utility is believable to a person of ordinary skill in the art based on the totality of evidence and reasoning provided). An assertion is credible unless (A) the logic underlying the assertion is seriously flawed, or (B) the facts upon which the assertion is based is inconsistent with the logic underlying the assertion. Credibility as used in this context refers to the reliability of the statement based on the logic and facts that are offered by the applicant to support the assertion of utility. A *credible* utility is assessed from the standpoint of whether a person of ordinary skill in the art would accept that the recited or disclosed invention is currently available for such use. For example, no perpetual motion machines would be considered to be currently available. However, nucleic acids could be used as probes, chromosome markers, or forensic or diagnostic markers. Therefore, the credibility of such an assertion would not be questioned, although such a use might fail the *specific* and *substantial* tests (see below).
>
> "Specific Utility" - A utility that is *specific* to the subject matter claimed. This contrasts with a *general* utility that would be applicable to the broad class of the invention. For example, a claim to a polynucleotide whose use is disclosed simply as a "gene probe" or "chromosome marker" would not be considered to be *specific* in the absence of a disclosure of a specific DNA target. Similarly, a general statement of diagnostic utility, such as diagnosing an unspecified disease, would ordinarily be insufficient absent a disclosure of what condition can be diagnosed.

"Substantial utility" - a utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities. For example, both a therapeutic method of treating a known or newly discovered disease and an assay method for identifying compounds that themselves have a "substantial utility" define a "real world" context of use. An assay that measures the presence of a material which has a stated correlation to a predisposition to the onset of a particular disease condition would also define a "real world" context of use in identifying potential candidates for preventive measures or further monitoring. On the other hand, the following are examples of situations that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use and, therefore, do not define "substantial utilities":

A. Basic research such as studying the properties of the claimed product itself or the mechanisms in which the material is involved.

B. A method of treating an unspecified disease or condition. (Note, this is in contrast to the general rule that treatments of specific diseases or conditions meet the criteria of 35 U.S.C. § 101.)

C. A Method of assaying for or identifying a material that itself has no "specific and/or substantial utility".

D. A method of making a material that itself has no specific, substantial, and credible utility.

E. A claim to an intermediate product for use in making a final product that has no specific, substantial, and credible utility.

Note that "throw away" utilities do not meet the tests for a *specific* or *substantial* utility. For example, using transgenic mice as snake food is a utility that is neither specific (all mice could function as snake food) nor substantial (using a mouse costing tens of thousands of dollars to produce as snake food is not a "real world" context of use). Similarly, use of any protein as an animal food supplement or a shampoo ingredient are "throw away" utilities that would not pass muster as specific or substantial utilities under 35 U.S.C. § 101. This analysis should, or course, be tempered by consideration of the context and nature of the invention. For example, it a transgenic mouse was generated with the specific provision of an enhanced nutrient profile, and disclosed for use as an animal food, then the test for specific and substantial *asserted* utility would be considered to be met.

"Well established utility" - a specific, substantial, and credible utility which is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art. "Well established utility" does not encompass any "throw away" utility that one can dream up for an invention or a nonspecific utility that would apply to virtually every member of a general class of materials, such as proteins or DNA. If this is the case, any product or apparatus, including perpetual motion machines, would have a "well established utility" as landfill, an amusement device, a toy, or a paper weight; any carbon containing molecule would have a "well established utility" as a fuel since it can be

> burned; any protein would have well established utility as a protein supplement for animal food. This is not the intention of the statute.

[See also the MPEP at § 2107 - 2107.02].

The claimed nucleic acid and oligonucleotides comprising the claimed polymorphism, G/C at position 21 are not supported by a substantial utility because the disclosed uses of the nucleic acid and oligonucleotide **have not** been established for the claimed subject matter.

As set forth above, a substantial utility defines a utility that is "real world" use. In other words, utilities that ***require*** or constitute carrying out further research to identify or reasonably confirm a "real world" use are **not substantial utilities.**

The specification states that the nucleic acid sequences and their disclosed polymorphisms (including the elected SEQ ID NO: 57) were isolated from two *Brassica* species, wherein said species are, "*B. napus* and *B. oleracea* using oligonucleotide primers designed from expressed DNA sequences from *Arabidopsis thaliana*, a relative of *Brassica napus* and member of the *Cruciferae* family (page 7, lines 10-13). Beginning at page 12, the specification discusses the preparation of the samples, detection of polymorphisms in target DNA (page 13) via use of well-know mean, such as ASO (page 13), arrays (page 14), allele specific primers (page 14), etc.

The specification also discusses that after the polymorphisms are found, this information can be used in a number of methods, such as fingerprint analysis (page 16), wherein said fingerprint analysis is described as, "useful in determining of which strain the plant is a member an [*sic*] in distinguishing one strain from another.

However, absent further research, whether the claimed polymorphism is useful as identifying a specific strain, would not be possible.

The specification only disclose that the nucleic acids containing polymorphisms were identified, but fails to disclose whether the identified polymorphisms were specific to the species *B. napus* or *B. oleracea*. The specification also fails to disclose whether the identified polymorphisms were generally found in said species. Absent such guidance and evidence, one skilled in the art would need to conduct further experimentation to reasonably identify whether the claimed polymorphism would be, if at all, useful in distinguishing specific strains.

In Brenner v. Manson, 383 U.S. 519, 535-536 (1996), the court expressed that when "[c]ongress intended that no patents be granted on a chemical compound whose sole "utility" consists of its potential role as an object of use-testing...a patent is not a hunting license. It is not a reward for the search, ***but compensation for its successful conclusion***."

The need of further research to identify an immediate application of the nucleic acid comprising SEQ ID NO: 57, containing a polymorphic site at 21st nucleotide from the 5' end, wherein said polymorphic site is either C or G, as discussed above, clearly demonstrates that the "successful conclusion" of the claimed subject matter has not been established.

As the claimed nucleic acid does not have utility, the method of using said nucleic acid would also fail under the utility requirement. For example, claim 15 is drawn to a nucleic acid obtained from a plurality of subjects, wherein said method tests for the claimed polymorphism, correlating the presence of the polymorphism with a phenotype.

However, absent a clearly demonstrated substantial utility, such methods would also fail to have substantial utility for the following reasons.

As recited above, the claimed methods are analogous to the situations described in MPEP (cited above):

A. Basic research such as studying the properties of the claimed product itself or the mechanisms in which the material is involved.

The claimed methods would fall under the above category, wherein the correlation of a phenotype for the claimed nucleic acid comprising the claimed polymorphism, would be nothing more than studying the properties of the claimed product; or

C. A Method of assaying for or identifying a material that itself has no "specific and/or substantial utility".

The specification does not disclose any phenotype associated with the claimed nucleic acid comprising the claimed polymorphism, hence the method, at best, would be identifying an unknown condition via use of the claimed nucleic acid.

For the above reasons, as the claimed subject matter fails to a patentable utility.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-15 are also rejected under 35 U.S.C. § 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention.

Claims 1-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not

described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a Written Description Rejection.

Preliminarily, the rejection applied to the extent of the elected subject matter, that is, the elected SEQ ID Number 57.

Claims 1-12 are drawn to ***any*** nucleic acid segments or oligonucleotides comprising a specific number of contiguous nucleotides which comprises ***any*** polymorphic site, and its method of using.

The specification discloses a nucleic acid consisting of SEQ ID NO: 57 (29-N1/10E12/N2-2), which is 41 nucleotides in length (page 9, specification), having a polymorphic site at 21st nucleotide from the 5' end, wherein said polymorphic site is either C or G. The instant specification defines this polymorphic site by use of brackets, "[ ]," wherein the, "upper and lower sequences in the square brackets are from the two strains being compared (upper strand corresponding to the first designated stran)." (page 7, line 37 to page 8, line 2).

However, the claim is drawn to a nucleic acid segment comprising at least 10 sequences of SEQ ID NO: 57, including ***any*** polymorphic site, which would ultimately embrace a nucleic acid that is larger than SEQ ID NO: 57 comprising any polymorphisms, so long as the nucleic acid comprises at least 10/50/20 sequences in common to SEQ ID NO: 57.

The specification does not describe a representative number of species (i.e., polymorphisms) embraced by claimed genus of nucleic acids and oligonucleotides.

The written description requirement ensures that, "an applicant invented the subject matter which is claimed. Further, the written description requirement for a claimed genus may

be satisfied *through a* sufficient description of *a representative number of species* by 1) reduction to practice; 2) reduction to drawing; or 3) disclosure of relevant identifying characteristics (*i.e.*, structure of other physical and/or chemical properties, functional characteristics *coupled* with a known or disclosed correlation between function and structure) (MPEP 2163 at II(A)(3)(a)(ii)).

Reduction to Practice

Although the specification discloses a single polymorphic site, G/C at position 21 (counting from the 5' end of SEQ ID NO: 57), the claims embrace a genus of nucleic acid which is larger than SEQ ID NO: 57 comprising ***any*** polymorphisms, so long as the nucleic acid comprises at least 10/50/20 sequences in common to SEQ ID NO: 57, wherein said nucleic acid could reasonably be drawn to nucleic acids from different species, none of which had been isolated nor contemplated by Applicants.

Reduction to Drawing

The specification discloses SEQ ID NO: 57, which is 41 nucleotides in length, comprising a single polymorphic site at position 21 (counting from the 3' end of SEQ ID NO: 57.

Disclosure of Relevant Identifying Characteristics

While one could argue that a skilled artisan would be able to identify the "representative number of species" of the remaining polymorphisms embraced by the claimed nucleic acid, such method would not satisfy the written description for the genus claims when, "the claims require an essential or critical feature which is not adequately described in the specification and which is

not conventional in the art or known to one of ordinary skill in the art" (MPEP 2163(I)(A)). For the claims at issue, such essential or critical feature is the polymorphism. Applicants have not disclosed enough number of species within the claimed genus of nucleic acids comprising ***any*** polymorphisms.

As stated in *University of California v. Eli Lilly and Co.* at page 1404:

> An adequate written description of a DNA ... "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel*, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, ***"an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it***; what is required is a description of the DNA itself." *Id.* at 1170, 25 USPQ2d at 1606.

Therefore, for the foregoing reasons, the genus embraced by the claims is not sufficiently described by the number of species disclosed in the specification, and therefore, the specification lacks written description of the claims.

Amending the claim to recite the elected SEQ ID Number and the elected polymorphism would overcome this rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 4, and 8-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Newman et al., (Plant Physiology, 1994, vol. 106, pages 1241-1255).

Newman et al. disclose an isolated nucleic acid comprising at least 10 contiguous nucleotides to SEQ ID NO: 57, comprising the base "C" at the polymorphic site identified in Table 1. Table 1 identifies either "C" or "G" as polymorphic nucleotide for the identified position. Hence, the nucleic acid disclosed by Newman et al. comprises the claimed polymorphsim.

The nucleic acid of Newman et al. is disclosed as having an overall homology of 92.7%, which would necessarily hybridize to the nucleic acid of SEQ ID NO: 57. The claims recite that the oligonucleotide "hybridizes" to the nucleic acid of Table 1 (in the instant case, the elected nucleic acid of SEQ ID NO: 57), as the claim does not set forth any specific conditions as to preclude non-specific hybridization of the nucleic acids, based on a reasonable broadest interpretation of the claims, the nucleic acid disclosed by Newman et al. would necessarily anticipate the claimed invention.

Conclusion

No claims are allowed.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (571) 272-0785. The Examiner can normally be reached from 8:30 a.m. to 6:00 p.m. Monday through Thursday. If attempts to reach the Examiner by telephone are unsuccessful, the Primary Examiner in charge of the prosecution, Dr. Kenneth Horlick, can be reached at (571) 272-0784. If the attempts to reach the above Examiners are unsuccessful, the Examiner's supervisor, Gary Benzion, can be reached at (571) 272-0782. Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in

the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. All official documents must be sent to the Official Tech Center Fax number: (571) 273-8300. For Unofficial documents, faxes can be sent directly to the Examiner at (571) 273-0785. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Young J. Kim
Patent Examiner
Art Unit 1637
12/27/04

yjk